

# **EXHIBIT 4**

**EXPERT REPORT**

**DAVID A. KESSLER, M.D.**

# Appendix D

**MATERIALS CONSIDERED**<sup>1</sup>

**Beginning Bates No.(Entire Bates Range considered)**

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<sup>1</sup> This appendix was prepared by legal staff at my request and subject to my review.

ABTDOT001278025  
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**Deposition Exhibits (not otherwise set forth in Beginning Bates No. section)**

Deposition Exhibit 36  
Deposition Exhibit 48  
Deposition Exhibit 52  
Deposition Exhibit 591  
Deposition Exhibit 602  
Deposition Exhibit 603  
Deposition Exhibit 605  
Deposition Exhibit 683  
Deposition Exhibit 700  
Deposition Exhibit 799  
Deposition Exhibit 880  
Deposition Exhibit 913  
Deposition Exhibit 914  
Deposition Exhibit 918  
Deposition Exhibit 920  
Deposition Exhibit 922

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Additional articles considered are set forth in Schedules 13, 18, and 19 of this Report

### **OTHER**

All documents cited in this Report and Schedules

FDA statutes, guidances, regulations and websites

Files and documents, including but not limited to Depakote IND/NDA SNDA files, were accessed and searched online via the litigation document database (Relativity)

### **AERs and PADERS**

ABTPAW000114383  
APTPAW000146759  
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APTPAW000352762  
APTPAW000487523  
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APTPAW000605525  
APTPAW000605526  
APTPAW000751137  
APTPAW000753996  
APTPAW000770238

### **Specific statutory sections considered**

21 CFR 200  
21 CFR 201 (1999)  
21 CFR 201 (2006)  
21 CFR 201 (2015)  
21 CFR 202  
21 CFR 203  
21 CFR 310  
21 CFR 312  
21 CFR 314  
21 CFR 600  
21 CFR 601  
21 U.S.C. 352  
21 U.S.C. 355 (FDCA 505)

71 Fed. Reg. 3922  
73 Fed. Reg. 49605

**Specific statutory sub-sections considered**

21 CFR 200.5  
21 CFR 201.56  
21 CFR 201.57 (1999)  
21 CFR 201.57 (2005)  
21 CFR 201.57 (2006)  
21 CFR 201.57 (2015)  
21 CFR 201.80  
21 CFR 314.70  
21 CFR 314.80  
21 CFR 314.81  
21 CFR 600.80  
21 CFR 600.81

*Feldman v. Lederle Lab.*, 125 N.J. 117, 121 (N.J. 1991)  
*Hill v. Searle Labs*, 884 F.2d 1064, 1068 (8th Cir. 1989)  
*Mutual Pharmaceutical Co. Inc. v. Bartlett* (2013) 133 S.Ct. 2466, 2480  
*Thomas v. Winchester*, 6 N.Y. 397 (1852)  
*Vautour v. Body Masters Sports Indus.*, 147 N.H. 150, 153-54 (2001)  
*Wells v. Ortho Pharm. Corp.*, 788 F.2d 741, 746 (11th Cir. 1986)  
*Wyeth v. Levine*, 555 U.S. 555, 567 (2009)

Abbvie Code of Business Conduct at 18, *available at*  
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Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use (21 CFR 314 & 601)

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Valpro (by Alphapharm) Production Information Sheet (2015), available at <http://www.medicines.org.au/files/afpvalpr.pdf>

Epival 2015 Product Monograph, available at <http://www.abbott.ca/docs/EPIVAL-PM-E.pdf>

Epival Label (2002)

Epival Label (2004)

Epilim Label (2003)

Abbott's Depakene/Depakote Labels-1979-2015

Pregnancy Category D Labels-*see* Schedule 7 of this Report

Labels for alternative therapies for the types of epilepsy and phases of bipolar for which Depakote is indicated-*see* Schedule 11 of this Report

### **Annual Reports**

Abbott Annual Reports for Depakote-*see*, in part, Schedule 10 of this Report

APTPAW000133819

APTPAW000427571

APTPAW000473733

APTPAW000522848

APTPAW000544498

APTPAW000547761

APTPAW000584976

APTPAW000694104

APTPAW000811383

APTPAW000933903

APTPAW000943870

### **FDA Communications**

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ABTPAW000933924  
ABTPAW000943871  
ABTPAW000950018  
ABTPAW000996211  
ABTPAW001000852  
APTPAW000708941  
Dear Doctor Letter (1982)  
Deposition Exhibit 36  
Deposition Exhibit 602  
Deposition Exhibit 683

**INDs**

ABTDOT000305247  
ABTPAW00084575  
ABTPAW000849492  
APTPAW000811536

**NDA & sNDAs**

ABTILSD002588002  
ABTPAW000132074  
ABTPAW000219642  
ABTPAW000219850  
ABTPAW000219918  
ABTPAW000220642  
ABTPAW000577645  
ABTPAW000582259  
ABTPAW000687521\_001  
ABTPAW000737220  
ABTPAW000996963

**Expert Reports**

1/17/2016 Expert Report of Dr. David Madigan

**Depositions and Exhibits**

10/29/13 Deposition of Blasine Penkowski including all exhibits  
11/21/13 Deposition of Lee Muraoka including all exhibits  
11/22/13 Deposition of Lee Muraoka including all exhibits  
12/3/13 Deposition of James Embrescia including all exhibits  
12/4/13 Deposition of James Embrescia including all exhibits  
12/10/13 Deposition of Michael Murray including all exhibits  
1/13/14 Deposition of Tracy Heimberger including all exhibits  
1/14/14 Deposition of Tracy Heimberger including all exhibits  
1/15/14 Deposition of Brian Enright including all exhibits  
2/12/14 Deposition of James Embrescia including all exhibits  
2/13/14 Deposition of Michael Jarvis including all exhibits  
2/14/14 Deposition of Michael Jarvis including all exhibits  
2/14/14 Deposition of James Steck including all exhibits  
4/24/14 Deposition of Michael Jarvis including all exhibits  
4/25/14 Deposition of Tracy Heimberger including all exhibits  
4/29/14 Deposition of Lee Muraoka including all exhibits  
4/29/14 Deposition of Michael Murray including all exhibits  
6/25/14 Deposition of Jeffrey Baker including all exhibits  
7/17/14 Deposition of Scott Luce including all exhibits  
7/31/14 Deposition of Michael LaFond including all exhibits  
8/13/14 Deposition of Lawrence Carbone including all exhibits  
12/11/14 Deposition of James Embrescia including all exhibits  
1/22/15 Deposition of Michael Jarvis including all exhibits